UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Axcan Scandipharm Inc.,

Plaintiff,

Civ. No. 07-2556 (RHK/JSM)
MEMORANDUM OPINION AND ORDER

v.

Ethex Corporation, KV Pharmaceutical Company, Global Pharmaceuticals, and Impax Laboratories, Inc.,

Defendants.

Ronn B. Kreps, Andre T. Hanson, Fulbright & Jaworski LLP, Minneapolis, Minnesota, Saul H. Perloff, Fulbright & Jaworski LLP, San Antonio, Texas, Marc B. Collier, Fulbright & Jaworski LLP, Austin, Texas, for Plaintiff.

William Z. Pentelovitch, Martin S. Fallon, Haley N. Schaffer, Maslon Edelman Borman & Brand LLP, Minneapolis, Minnesota, Thomas C. Morrison, Robert W. Lehrburger, John C. Knapp, Patterson Belknap Webb & Tyler LLP, New York, New York, for Defendants Ethex Corporation and KV Pharmaceutical Company.

John B. Lunseth, Briggs and Morgan, P.A., Minneapolis, Minnesota, Claude M. Stern, Scott B. Kidman, Quinn Emanuel Urquhart Oliver & Hedges, LLP, Los Angeles, California, for Defendants Impax Laboratories, Inc. and Global Pharmaceuticals.

INTRODUCTION

The Plaintiff in this Lanham-Act action, Axcan Scandipharm, Inc. ("Axcan"), manufactures and markets the "Ultrase" line of pancreatic-enzyme-supplement drugs. Defendants Ethex Corporation ("Ethex") and KV Pharmaceutical Company ("KV") manufacture and sell a "generic" line of Ultrase called "Pangestyme." Similarly,

Defendants Impax Laboratories, Inc. ("Impax") and Global Pharmaceuticals ("Global") manufacture and sell a different "generic" line of Ultrase called "Lipram." In this action, Axcan alleges that Ethex, KV, Impax, and Global have engaged in false advertising and unfair competition under the Lanham Act, 15 U.S.C. § 1051 *et seq.*, and Minnesota law because neither Pangestyme nor Lipram is truly a "generic equivalent" version of Ultrase. Ethex and KV now move for judgment on the pleadings, while Impax and Global move to dismiss. For the reasons set forth below, the Motions will be granted in part and denied in part.

BACKGROUND

Since the early 1990's, Axcan has manufactured and marketed its Ultrase line of pancreatic-enzyme drugs. (Compl. ¶ 1.) These drugs help patients with pancreatic insufficiencies – such as those suffering from cystic fibrosis or chronic pancreatitis – who are unable to produce the enzymes necessary to break down and digest fats, proteins, and carbohydrates in the foods they eat. (Id. ¶¶ 18-26.) Ultrase contains those needed enzymes and comes in three formulations – Ultrase MT12, Ultrase MT18, and Ultrase MT20 – which correspond to the amount of a certain pancreatic enzyme (lipase) contained in each. (Id. ¶ 27.)

In addition to Ultrase, there are two other major brand-name lines of pancreatic-enzyme supplements: "Creon," which is sold by Solvay Pharmaceuticals ("Solvay"), and "Pancrease," which is sold by Ortho-McNeil. Creon and Pancrease also come in different

formulations, based on the amount of lipase they contain.[1]

In August 2000, KV began to manufacture, and Ethex began to sell, Pangestyme, an allegedly "generic equivalent" version of Ultrase, in three formulations: Pangestyme-UL12, Pangestyme-UL18, and Pangestyme-UL20. (Id. ¶ 35.) Likewise, in April 1999, Global and Impax began to manufacture and sell their own "generic equivalent" version of Ultrase – Lipram – in three similar formulations. (Id. ¶ 44.)[2] Axcan alleges that the Defendants advertise their pancreatic-enzyme drugs as being "identical in formulation to Ultrase" even though they contain different amounts of lipase and other pancreatic enzymes from Ultrase. (Id. ¶¶ 32, 46.) Axcan further alleges that the Defendants invite pharmacists and others to compare the labeled ingredients in their drugs with Ultrase, and thereby imply that those drugs are "generic equivalent substitute[s] for Ultrase," when in fact they contain different formulations. (Id. ¶¶ 38, 47.) Accordingly, Axcan alleges that Ethex, KV, Impax, and Global have engaged in false advertising and unfair competition, leading "pharmacists in Minnesota and across the country . . . into believing that Lipram-UL and Pangestyme-UL are generic equivalents to Ultrase and [to] substitute[] Pangestyme-UL and Lipram-UL for Ultrase as a result." (Id. ¶ 61.)

This is not the first time that such allegations have been levied against the

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[1] Although Ultrase, Creon, and Pancrease all come in formulations containing the same amount of lipase, they differ in that they contain unique amounts of other pancreatic enzymes (amylase and protease). (Compl. ¶ 30 & n.3.)

[2] According to the Complaint, Ethex is a wholly-owned subsidiary of KV and is responsible for marketing KV's "generic" drugs. (Compl. ¶ 9.) Similarly, Global is Impax's "generic marketing division" and Impax "controls and directs" Global's operations. (Id. ¶ 11.)

Defendants. In 2003, Solvay filed lawsuits in this Court against Ethex and KV (Civil No. 03-2836 (Tunheim, J.) ("Solvay I")) and Impax and Global (Civil No. 03-2854 (Frank, J.) ("Solvay II")) alleging nearly identical claims to those asserted by Axcan here.[3] Impax and Global settled Solvay II; after almost four years of litigation, Solvay I resulted in a defense verdict following a six-week jury trial.[4]

Ethex and KV now move for judgment on the pleadings, while Impax and Global move to dismiss. In their Motion, Ethex and KV argue that (1) the Food and Drug Administration ("FDA") has "primary jurisdiction" over Axcan's claims; (2) Axcan's claims are beyond the applicable statutes of limitations; (3) Axcan's claims are barred by *res judicata*; and (4) Axcan's claims are barred by laches. Impax and Global make similar arguments in their Motion, and also assert that (1) marketing one drug as an "alternative" to another, or asking consumers to "compare" two drugs, cannot be "false advertising" as a matter of law, and (2) Axcan's claims are not pleaded with sufficient particularity under Federal Rule of Civil Procedure 9(b). In addition, Ethex and KV have adopted as their own

[3] It is unclear why this case and the Solvay cases were commenced in Minnesota. Axcan is headquartered in Alabama, Solvay is headquartered in Georgia, KV and Ethex are headquartered in Missouri, Impax is headquartered in California, and Global is headquartered in Pennsylvania. Because the alleged false advertising and unfair competition occurred nationwide, the Defendants are subject to personal jurisdiction and venue in any of the 50 states. Accordingly, one would expect Axcan and Solvay to file their lawsuits in their home forums and not Minnesota, which has no obvious connection to the parties or the claims.

[4] Solvay's lead counsel, Saul Perloff of the law firm Fulbright & Jaworski LLP, represents Axcan in this case.

the arguments raised by Impax and Global, and vice versa.[5]

STANDARD OF REVIEW

Ethex's and KV's Motion for Judgment on the Pleadings is reviewed under the same standard as Impax's and Global's Motion to Dismiss. Westcott v. City of Omaha, 901 F.2d 1486, 1488 (8th Cir. 1990). In Bell Atlantic Corp. v. Twombly, __ U.S. __, 127 S. Ct. 1955 (2007), however, the Supreme Court recently altered the legal landscape for evaluating a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6).[6]

To avoid dismissal under Rule 12(b)(6), a complaint must include "enough facts to state a claim to relief that is plausible on its face." Id. at 1974. While Rule 8 of the

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[5] Pursuant to Local Rule 7.1(c), a party filing a dispositive motion is limited to a total of 12,000 words between its opening memorandum *and* its reply memorandum. By adopting the arguments made by the other Defendants in their moving papers, all of the Defendants have violated the spirit, if not the letter, of this Local Rule.

[6] The Court pauses to note that Ethex and KV previously moved for judgment on the pleadings and, in support of that Motion, submitted a plethora of documents outside the pleadings. Ethex and KV then moved to withdraw their Motion. The Court granted the Motion to Withdraw and, at that time, advised Ethex and KV that matters outside the pleadings are not appropriately considered by the Court when resolving such a motion. (See July 27, 2007 Order (Doc. No. 32) at 2 n.1.)

In their re-filed Motion for Judgment on the Pleadings, Ethex and KV apparently ignored the Court's warning; they have once again submitted a large number of documents beyond the pleadings in support of their Motion. The Court declines to consider those documents. See Fed. R. Civ. P. 12(c). Regardless, most of the issues raised in Ethex's and KV's Motion are purely legal matters, which are unaffected by the documents Ethex and KV have submitted.

Taking a slightly different tack, Impax and Global have asked the Court to take judicial notice of the Complaints filed in Solvay I and Solvay II, the docket sheet in Solvay II, and a webpage from the Food and Drug Administration. (Doc. No. 43.) Insofar as these are all matters appropriate for judicial notice, that request is **GRANTED**. See Great Plains Trust Co. v. Union Pac. R.R. Co., 492 F.3d 986, 995-96 (8th Cir. 2007) (court may take judicial notice of proceedings in other cases, as well as agency documents). Nevertheless, these matters are of limited assistance to the Court in connection with the instant Motions.

Federal Rules of Civil Procedure does not require the pleading of "detailed factual allegations," a plaintiff nevertheless must plead sufficient facts "to provide the 'grounds' of his 'entitle[ment] to relief,' [which] requires more than labels and conclusions, and [for which] a formulaic recitation of the elements of a cause of action will not do." Id. at 1964-65 (citation omitted). Thus, a complaint cannot simply "le[ave] open the possibility that a plaintiff might later establish some 'set of undisclosed facts' to support recovery." Id. at 1968 (citation omitted). Rather, the facts set forth in the complaint must be sufficient to "nudge the[] claims across the line from conceivable to plausible." Id. at 1974.

When reviewing a motion to dismiss, the complaint must be liberally construed, assuming the facts alleged therein as true and drawing all reasonable inferences from those facts in the plaintiff's favor. Id. at 1964-65. A complaint should not be dismissed simply because the court is doubtful that the plaintiff will be able to prove all of the factual allegations contained therein. Id. Accordingly, a well-pleaded complaint will survive a motion to dismiss "'even if it appears that a recovery is very remote and unlikely.'" Id. at 1965 (citation omitted).

ANALYSIS

I. The Court enjoys subject-matter jurisdiction over Axcan's claims.

The Court begins its analysis with the Defendants' arguments concerning subject-matter jurisdiction. See Bell v. Hood, 327 U.S. 678, 682 (1946) ("Whether the complaint states a cause of action on which relief could be granted is a question of law [that] must be decided after and not before the court has assumed jurisdiction over the controversy.");

Ramming v. United States, 281 F.3d 158, 161 (5th Cir. 2001) (a district court "should consider [a] jurisdictional attack before addressing any attack on the merits"). The Defendants argue that the Court lacks jurisdiction over Axcan's claims because the FDA has primary responsibility for regulating pancreatic-enzyme-drug marketing.[7] This argument was rejected in both Solvay I and Solvay II. Rather than painting on a blank palette, the Court will quote extensively from Judge Tunheim's succinct recitation of the controlling legal framework in Solvay I:

A. The FDCA and FDA

> The primary regulatory system covering prescription drugs was created by the Food, Drug and Cosmetic Act ("FDCA"). 21 U.S.C. § 301-92. The FDCA requires FDA approval, through a "new drug application" ("NDA"), before a new drug may be put on the market. Id. at §§ 331(d), 355(a). A product similar to an NDA approved drug may be approved and marketed based on an "abbreviated new drug application" ("ANDA"). Id. at § 355(j). An ANDA requires the manufacturer of the similar drug to demonstrate that the two drugs are therapeutically equivalent, that is pharmaceutically equivalent and bioequivalent. Id. at § 355(j)(2)(A)(i)-(viii).[8] Each year the FDA publishes Approved Drug

[7] The Defendants label this argument differently, with Ethex and KV asserting that Axcan's claims fall within the FDA's exclusive jurisdiction (Ethex & KV Mem. at 31-44), while Impax and Global assert that the claims are "precluded" by the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (Impax & Global Mem. at 5-18). Despite the semantic differences, it is clear that these arguments are one-and-the-same. (Compare Ethex & KV Mem. at 34 ("If Ethex is unlawfully marketing Pangestyme as a generic, that is a matter for the FDA, not a private litigant.") with Impax & Global Mem. at 7-8 ("Axcan's complaint is that Impax may not lawfully market or sell Lipram as a generic version of . . . Ultrase . . . . That, however, is a matter that falls squarely within the primary jurisdiction of the FDA and, as a matter of law, cannot be the subject of a private right of action.").)

[8] Two drugs are considered "pharmaceutically equivalent" if they have the same active ingredients, strength, and dosage, while two drugs are considered "bioequivalent" if they do not have significantly different rates and extent of absorption in the body. See 21 C.F.R. § 320.1(c), (e); Preface to the Twenty-Second Edition, Approved Drug Products with Therapeutic Equivalence Evaluations, available at http://www.fda.gov/cder/orange/adppreface.htm.

Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book," listing all NDA approved drugs along with therapeutic equivalence determinations. Enforcement of the FDCA is permitted exclusively "by and in the name of the United States" or, in certain circumstances, by a state. 21 U.S.C. § 337; see Sandoz Pharms. Corp. v. Richardson-Vicks, Inc., 902 F.2d 222, 231 (3rd Cir. 1990) (FDA and FTC share exclusive jurisdiction over regulation of drug marketing requiring original interpretation of FDA or FTC acts or regulations).

Prescription pancreatic enzyme supplements are, like any other drug, subject to FDA regulation. In 1995 the FDA declared that all pancreatic enzyme drugs would require NDA or ANDA approval, but permitted such drugs to remain on the market while the FDA fleshed out the approval process. Thus, neither Creon [Solvay's brand-name pancreatic-enzyme drug] nor Pangestyme [Ethex's and KV's "generic"] has been tested, approved, compared or otherwise passed on by the FDA, and neither is listed in the Orange Book.

B. The Lanham Act

The Lanham Act provides a private remedy to a plaintiff who has been harmed by "commercial advertising or promotion" that "misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities." 15 U.S.C. § 1125(a)(1)(B). The Act primarily protects commercial interests of individuals. Sandoz, 902 F.2d at 230. In contrast to the FDCA, the Lanham Act expressly establishes a private right of action. See 15 U.S.C. § 1125(a). Ethex markets Pangestyme to doctors, pharmacists, drug wholesalers, and drug retailers.

C. Overlap

The FDCA and the Lanham Act overlap to the extent that both regulate drug products in the marketplace. Courts have recognized the potential conflict between the two Acts and have struggled to define the proper scope of each law. Courts have come to the general conclusion that the FDA's enforcement of the FDCA is primarily concerned with the safety and efficacy of new drugs, while the Lanham Act is focused on the truth or falsity of advertising claims. See, e.g., Sandoz, 902 F.2d at 230. More specifically, where a claim requires interpretation of a matter that is exclusively within the jurisdiction and expertise of the FDA and FDCA, plaintiffs cannot use the Lanham Act as a backdoor to private enforcement. Id. at 231; Mylan Labs., Inc. v. Matkari, 7 F.3d 1130, 1139 (4th Cir. 1993). However, "false statements are actionable under the Lanham

Act, even if their truth may be generally within the purview of the FDA." Solvay I, 2004 WL 742033, at *2-3 (D. Minn. Mar. 30, 2004) (footnote 8 added by this Court) (citations and footnotes omitted); see also Solvay II, 298 F. Supp. 2d 880, 883-85 (D. Minn. 2004).

Here, as in Solvay, the Defendants argue that, by challenging their marketing of Pangestyme and Lipram as "generic equivalents to" or "substitutes for" Ultrase, Axcan has necessarily asserted that the Defendants are improperly representing their drugs as "equivalent" to Ultrase *in the FDA's sense of that term* – in other words, the Defendants understand Axcan's claims to mean that the Defendants are improperly suggesting that Pangestyme and Lipram are pharmaceutically equivalent and bioequivalent to Ultrase. (See Impax & Global Mem. at 8; Ethex & KV Mem. at 33-34.) According to the Defendants, whether their drugs are "equivalent" to Ultrase in such fashions can only be determined by the FDA.

The Defendants, however, misapprehend the nature of Axcan's claims. Axcan does not allege that the Defendants have falsely implied that their drugs are "equivalent" in the FDA sense – that is, bioequivalent and pharmaceutically equivalent to Ultrase. Rather, Axcan asserts that, by advertising their drugs as "generic equivalents to" or "substitutes for" Ultrase, the Defendants have engaged in false advertising based on "the proper market definition[s]" of these terms. (Mem. in Opp'n at 18.) Stated differently, Axcan seeks to proffer evidence of the *generally understood meanings* of the terms "generic equivalence" and "substitute," and not the FDA's definition of "equivalence," in order to

establish the falsity of the Defendants' advertisements. Such claims in no way infringe on the FDA's right to determine whether two drugs are "equivalent" to one another based on *its* definition of "equivalence." See Solvay I, 2004 WL 742033, at *4 ("an FDA determination is not necessarily required in order for two drugs to be properly considered equivalent"); Solvay II, 298 F. Supp. 2d at 884-85.[9] Simply put, Axcan's claims do not require the Court "to determine anything within the particular jurisdiction of the FDA"; the claims do not concern "the safety and efficacy" of the Defendants' drugs, but rather "the truth or falsity of [their] advertising claims." Solvay I, 2004 WL 742033, at *3-4; accord Midlothian Labs., L.L.C. v. Pamlab, L.L.C., No. 2:04cv836, 2007 WL 2458409, at *14 (M.D. Ala. Aug. 28, 2007) (assertion that "'generic equivalence' is false advertising is not preempted by the FDA to the extent that [the counter-plaintiff] seeks to prove its claim with evidence that

[9] This is not to say that Axcan cannot use the FDA's definitions of bioequivalence or pharmaceutical equivalence when seeking to prove its claims. The FDA's "primary jurisdiction" does not prohibit a plaintiff from relying on the FDA's definitions "merely to establish the standard [that the] defendants allegedly failed to meet." Solvay I, 2004 WL 742033, at *4 (quoting Grove Fresh Distribs., Inc. v. Flavor Fresh Foods, Inc., 720 F. Supp. 714, 716 (N.D. Ill. 1989)); accord Alpharma, Inc. v. Pennfield Oil Co., 411 F.3d 934, 939 (8th Cir. 2005) (Lanham-Act claim may proceed even when it "turns on the meaning of [FDA] publications in the Federal Register and Code of Federal Regulations").

The Defendants argue that, in Solvay I, Solvay sought to prove its claims not by pointing to Ethex's and KV's advertising, but rather by arguing that Pangestyme could not be marketed as a "generic" version of Creon without a determination that Pangestyme meets *the FDA's* definition of "generic." (Ethex & KV Mem. at 31.) Assuming *arguendo* that the Defendants' description of Solvay's arguments is correct and that those arguments somehow infringed on the FDA's "primary jurisdiction," that would pose no hurdle to Axcan's claims here. Just because Solvay may have attempted to prove its claims in a certain fashion does not mean that Axcan will seek to replicate Solvay's methods of proof in this case, notwithstanding that Axcan is represented by the same counsel as Solvay.

pharmacists understand 'generic equivalence' to imply therapeutic equivalence (or some other standard of equivalence), rather than with evidence that FDA regulations require therapeutic equivalence"); Pediamed Pharms., Inc. v. Breckenridge Pharms., Inc., 419 F. Supp. 2d 715, 725-26 (D. Md. 2006).

Recognizing that they face an uphill battle due to Solvay I and Solvay II, the Defendants argue that those decisions are no longer good law in light of two subsequent cases: Alpharma, Inc. v. Pennfield Oil Co., 411 F.3d 934 (8th Cir. 2005), and Credit Suisse Securities (USA) LLC v. Billing, __ U.S. __, 127 S. Ct. 2383 (2007). Neither Alpharma nor Credit Suisse, however, aids the Defendants' cause.

In Alpharma, the plaintiff alleged that the defendant had violated the Lanham Act by advertising its antibiotic as approved for certain uses by the FDA, even though it had not been so approved. The district court dismissed the action based on the FDA's primary jurisdiction, but the Eighth Circuit reversed. The court held that the plaintiff's claim – that the defendant was improperly advertising that its product "*has* been approved as safe and effective" – turned simply on the truth or falsity of that assertion, and was much different from determining whether the defendant's product "*should be* approved as safe and effective," which was within the exclusive province of the FDA. 411 F.3d at 939 (emphases added). Since the plaintiff's claim turned only on the veracity of the defendant's advertising – *i.e.*, had the drug actually been proved safe and effective? – the court held that the claim was not barred. Id. Similarly, the issue here is not whether the FDA should deem the Defendants' products to be "generic" versions of Ultrase; rather, the issue is whether,

by advertising and marketing those products as "generic equivalents to" or "substitutes for" Ultrase when they do not contain the same ingredients, the Defendants' advertising is literally or implicitly false, based on commonly understood meanings of "equivalent" and "substitute." Nothing in Alpharma bars such a claim.

In Credit Suisse, the Supreme Court held that federal antitrust law must yield to federal securities law – in particular, regulations issued by the Securities and Exchange Commission ("SEC") – where the two are "clearly incompatible." 127 S. Ct. at 2392. The Court identified several factors used to determine whether the SEC's regulatory scheme precluded application of the antitrust laws, one of which is whether there exists a "serious conflict between the antitrust and regulatory schemes." Id. at 2397. According to the Defendants, Credit Suisse teaches that Axcan's Lanham-Act claims must yield to the FDA's regulatory scheme concerning generic drugs, but this Court does not agree.

Credit Suisse does not break any new ground, at least in the Lanham-Act context[10] – indeed, Solvay I and Solvay II each noted that federal courts have long struggled to resolve the interplay between the FDA's and the Lanham Act's regulation of drug marketing. Moreover, even if Credit Suisse somehow "heralds sweeping changes to existing precedent" (Mem. in Opp'n at 24), its holding would still be inapposite because there is no "serious conflict" between the FDA's regulations and Axcan's claims here. 127 S. Ct. at 2397. As discussed above, the claims in this case focus on the truth or falsity of the

[10] The Court's research has failed to unearth any cases applying Credit Suisse to Lanham-Act claims.

Defendants' advertising that their pancreatic-enzyme drugs are, among other things, "generic equivalents to" or "substitutes for" Ultrase, based on commonly understood meanings of those terms. Such claims can be maintained in this Court without infringing on the FDA's right to determine whether the Defendant's drugs are "generic" versions of Ultrase under its own definition of "equivalence." Simply put, there is no conflict here.[11]

Accordingly, Axcan's claims are not barred by the FDA's "primary jurisdiction."

II. The statute of limitations bars claims for conduct occurring prior to June 1, 2001.

The Lanham Act does not contain a statute of limitations. When a Lanham-Act defendant asserts that the plaintiff's claims are barred by the statute of limitations, a court must "look to the local statute which bears the closest resemblance to the [Lanham Act] and then apply the limitation period applicable to it." Fox Chem. Co. v. Amsoil, Inc., 445 F. Supp. 1355, 1358-59 (D. Minn. 1978) (Devitt, J.) (citations omitted); accord Island Insteel Sys., Inc. v. Waters, 296 F.3d 200, 206 (3rd Cir. 2002). For Lanham-Act claims, Minnesota federal courts borrow the six-year statute of limitations in Minnesota Statutes Section 541.05(2). See LensCrafters, Inc. v. Vision World, Inc., 943 F. Supp. 1481, 1491

[11] Axcan also alleges a claim that was not alleged in Solvay: that the Defendants advertise their drugs as meeting the quality standards promulgated by the United States Pharmacopeia (USP) when in fact they do not. (Compl. ¶¶ 40, 49, 64-65.) Clearly, a claim alleging that such advertising is false does not turn on the safety or efficacy of the Defendants' drugs, but rather turns on whether the Defendants' drugs do, in fact, meet USP standards. As with Axcan's other Lanham-Act claims, therefore, the claims based on such advertising are not preempted by the FDA's primary jurisdiction.

n.6 (D. Minn. 1996); Fox Chem., 445 F. Supp. at 1358.[12] Similarly, Axcan's state-law claims also are subject to a six-year statute of limitations. See, e.g., Klehr v. A.O. Smith Corp., 875 F. Supp. 1342, 1352-53 (D. Minn. 1995).

There is no dispute that some of the conduct challenged by Axcan occurred prior to June 1, 2001 (six years prior to the date the Complaint was filed). (See Mem. in Opp'n at 34.)[13] Nevertheless, Axcan argues that it can seek relief based on that conduct, relying on the "continuing-violation" doctrine. There are two types of continuing violations: those in which a defendant's plan, practice, or procedure causes unlawful acts to occur both outside and inside the limitations period (in which case the earlier violations are not time barred), and those in which an independent and distinct violation occurring outside the limitations period is repeated within the period (in which case the earlier violation is time barred). See, e.g., Mandy v. Minn. Mining & Mfg., 940 F. Supp. 1463, 1468 (D. Minn. 1996). Axcan attempts to shoehorn the Defendants' conduct into the first type of continuing violation and, hence, argues that Defendants' allegedly false advertising before June 1,

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[12] Claims under the Lanham Act – whether for damages or for injunctive relief – are subject "to the principles of equity." 15 U.S.C. §§ 1116(a), 1117(a). As a result, some courts and commentators have questioned whether Lanham-Act claims are subject to a laches defense, and not a statute-of-limitations defense, since the Lanham Act contains no limitations period and "[l]aches [is] an equitable defense [while] the statute of limitations [is] a creature of law." Jarrow Formulas, Inc. v. Nutrition Now, Inc., 304 F.3d 829, 835 (9th Cir. 2002); see also id. at 836-37 (collecting cases). Because all parties here agree that Axcan's Lanham-Act claims are subject to a statute of limitations (see Impax & Global Mem. at 21; Ethex & KV Mem. at 18-19; Axcan Opp. at 32), the Court need not opine on this issue.

[13] While the Complaint is dated May 31, 2001, it was filed on June 1, 2001.

2001 is actionable. The Court does not agree.[14]

"The term 'continuing violation' . . . implies that there is but one incessant violation and that the plaintiff[] should be able to recover for the entire duration of the violation, without regard to the fact that it began outside the statute of limitations window." Knight v. Columbus, Ga., 19 F.3d 579, 582 (11th Cir. 1994). Here, however, the challenged conduct was not the result of "one incessant violation," but rather was a "series of repeated violations of an identical nature," namely, the Defendants' repeated (false) advertising of their drugs as "generic equivalents to" and "substitutes for" Ultrase. Id. (continuing-violation doctrine not applicable to repeated failure to pay overtime to employees, since each failure constituted a new violation); see also Nat'l R.R. Passenger Corp. v. Morgan, 536 U.S. 101, 112 (2002) ("discrete acts that fall within the statutory time period do not make timely acts that fall outside the time period"); Pioneer Co. v. Talon, Inc., 462 F.2d 1106, 1108 (8th Cir. 1972) ("each time a plaintiff is injured by an act of the defendants a cause of action accrues to him to recover the damages caused by that act and . . . the statute of limitations runs from the commission of the act").

Moreover, the first type of continuing violation typically concerns an unlawful

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[14] Axcan also argues that the Court need not decide "at this early date" which type of continuing-violation theory applies to the Defendants' conduct. (Mem. in Opp'n at 32-34 (describing the issue as "academically interesting but premature" because it relates only to Axcan's potential damages).) Demarcating which advertisements are actionable, however, will narrow the issues for discovery and ultimately help to streamline the trial in this case. As evidenced by the Solvay cases, discovery in this case is likely to be both time-consuming and expensive. Paring down the scope of discovery, therefore, will be beneficial.

practice or procedure – Knight's so-called "incessant violation" – that spawns specific unlawful acts, such as a hostile work environment. See, e.g., Morgan, 536 U.S. at 120-21; Derrick Mfg. Corp. v. Sw. Wire Cloth, Inc., 934 F. Supp. 796, 808 (S.D. Tex. 1996) ("These claims are such that later violations are inseparable from the earlier ones and thus are all deemed a single wrong."). In such a situation, it is the policy that is unlawful, but neither the policy nor its unlawfulness becomes evident until specific unlawful acts caused by the policy have been repeated several times. See Morgan, 536 U.S. at 120 & n.12. Here, however, with each (allegedly) false advertisement, the Defendants' illegal conduct was manifest and Axcan could have sued; "where each [instance of wrongful conduct] is separate, distinct, and could have been challenged by a plaintiff, the continuing [violation] doctrine does not apply." Hope v. Klabal, 457 F.3d 784, 793 (8th Cir. 2006). Axcan has cited no Lanham-Act cases applying the first type of continuing violation, and the Court has found none.

Accordingly, the Court concludes that Axcan's claims are time barred insofar as they challenge conduct occurring prior to June 1, 2001.

III. It is too early to decide whether *res judicata* applies.

The Defendants next argue that Axcan's claims are barred by *res judicata* due to the defense verdict in Solvay I. "Under the doctrine of *res judicata*, a judgment on the merits in a prior suit bars a second suit involving the same parties or their privies based on the same cause of action." Daley v. Marriott Int'l, Inc., 415 F.3d 889, 895-96 (8th Cir. 2005). Although the claims here parallel the claims in Solvay I, Axcan was not a party to that

action. *Res judicata*, therefore, bars Axcan's claims only if it is "in privity" with Solvay.

The Defendants rely on the "virtual-representation" doctrine to argue that Axcan is in privity with Solvay. Under that doctrine, privity with a party to a prior lawsuit may exist if the latter party's interests were "adequately represented" by the litigant in the earlier case – that is, if the latter party's interests are "so closely aligned" with the prior party's interests that the prior party was, in essence, the latter party's "virtual representative." Tyus v. Schoemehl, 93 F.3d 449, 454 (8th Cir. 1996) (quoting Aerojet-Gen. Corp. v. Askew, 511 F.2d 710, 719 (5th Cir. 1975)). There is no bright-line rule to decide when to apply the "virtual-representation" doctrine; it is a fact-intensive inquiry aimed at determining whether the relationship between the party to the prior litigation and the party to the subsequent litigation is "close enough." Id. at 455 (quoting Gerrard v. Larsen, 517 F.2d 1127, 1134 (8th Cir. 1975)). This fact alone suggests that it would be inappropriate to dismiss Axcan's claims, at this early stage of the litigation and on an undeveloped factual record, based on Solvay's purported "virtual representation" of Axcan. See, e.g., EEOC v. Pemco Aeroplex, Inc., 383 F.3d 1280, 1287 (11th Cir. 2004) ("Whether or not a party is a virtual representative of another is a question of fact.").

In any event, courts look at several factors when deciding whether to apply the virtual-representation doctrine, including (1) identity of interests between the parties, (2) the closeness of the parties' relationship, (3) participation in the prior litigation, (4) acquiescence in the prior litigation, (5) whether the present party "deliberately maneuvered" to avoid the effects of the first action, (6) "adequacy of representation," that

is, whether the prior litigant had a "strong incentive" to protect the interests of the second party, and (7) whether a public-law issue or a private-law issue is raised. Id. at 455-56 (citations omitted). Despite the Defendants' best efforts to convince the Court otherwise, and although at least some of these factors appear to weigh in the Defendants' favor, at the present juncture the Court is not persuaded that these factors mandate the dismissal of Axcan's claims.

First, there is no basis for the Court to conclude that Solvay had a "strong incentive" – or any incentive at all – to "adequately represent" Axcan's interests in its prior litigation against the Defendants. Axcan and Solvay are competitors in the pancreatic-enzyme-drug market and, hence, their interests are not necessarily aligned. See Nordhorn v. Ladish Co., 9 F.3d 1402, 1405-06 (9th Cir. 1993) (holding that one company did not virtually represent another company in prior litigation, even though their interests were aligned, when there was "no indication that [the first company] had any interest in [the second company's] affairs or well-being during or after [its] lawsuit").[15] By the same token, it is difficult to conceive that Axcan and Solvay have a "close relationship" when they compete in the same market. Cf. Tyus, 93 F.3d at 457 (close relationship existed when second action involved some of the same plaintiffs as earlier action and all plaintiffs were St. Louis alderman suing

[15] By way of example here, Solvay may have been litigating against the Defendants in an attempt to strengthen its share of the pancreatic-enzyme market, to Axcan's potential detriment. See Kourtis v. Cameron, 419 F.3d 989, 997 (9th Cir. 2005) ("a conflict of interest between a non-party and his purported representative forecloses the possibility of privity").

to challenge aldermanic re-districting).[16] At this early stage of the proceedings, the Court simply does not have an adequate record upon which to determine whether Solvay's and Axcan's interests are aligned.

Second, even if it can be said that Solvay and Axcan share an identity of interests, that alone is not sufficient. Id. at 455. Rather, "it is necessary to show not just that [Solvay and Axcan] wanted the same results but also that [Solvay] had substantially the same incentive to achieve it." Taylor v. Blakey, 490 F.3d 965, 972 (D.C. Cir. 2007). At this motion-to-dismiss stage, there is no evidence before the Court upon which it could make such a determination. Cf. id. (at summary judgment, concluding that evidence demonstrated identity of interests and incentive to protect those interests).

Third, there is no evidence that Axcan participated in Solvay[17] or that it waited to

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[16] The Defendants point out that Axcan and Solvay have engaged the same counsel, but "use of the same counsel in itself is hardly dispositive" of whether a close relationship exists. Taylor v. Blakey, 490 F.3d 965, 974 (D.C. Cir. 2007) (citing S. Cent. Bell Tel. Co. v. Alabama, 526 U.S. 160, 167-68 (1999)).

[17] The Defendants argue that Axcan could have sought to intervene in Solvay (Ethex & KV Mem. at 30), and that this fact militates in favor of applying the virtual-representation doctrine. In fact, just the opposite is true. As the court noted in People Who Care v. Rockford Board of Education:

> *Res judicata* cannot bar [a party's] claim . . . unless [his] legal interests are so closely aligned with one or more of the parties that they are at least his virtual representatives. However, if he is so closely aligned with one or more of the parties that they are his virtual representatives, then his concerns have certainly received adequate representation. And, if his interests are represented, he need not intervene; in fact, he cannot intervene unless he *lacks* adequate representation by the existing parties. *Thus if [the party] may intervene because he lacks sufficient representation, then there is no privity and* res judicata *will not bar his claim.*

68 F.3d 172, 177 (7th Cir. 1995) (second emphasis added) (citations omitted). In any event, it is well-

bring this lawsuit out of a concern that Solvay would lose its litigation and, hence, "deliberately maneuvered" to avoid the effects of Solvay I. See Pemco, 383 F.3d at 1288 (deliberate maneuvering means "maneuvering to avoid preclusion").[18] Nor is there any evidence indicating that Axcan "acquiesced" in Solvay's litigation against the Defendants or agreed to be bound by the judgment obtained in Solvay I. See Restatement (Second) of Judgments § 40 cmt. b (1982 & Supp. 2007) (no agreement to be bound by judgment should be inferred "except upon the plainest circumstances").

Finally, the claims in this case do not, as the Defendants argue, raise public-law issues. The Defendants assert that the purported "false" advertising of their drugs raises a public interest because it calls into question "the safety and efficacy of pancreatic enzymes." (Ethex & KV Reply at 4-5.) However, what Axcan asserts in this case is simply a damages claim for false advertising, a mere "private right shared not in common with the public." Tyus, 93 F.3d at 457. Stated differently, an endless number of possible plaintiffs alleging the same claims as Axcan (and Solvay) do not exist. Rather, only a finite and limited number of entities may claim Lanham-Act damages as a result of the Defendants'

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settled that "[t]he law does not impose upon any person . . . the burden of voluntary intervention in a suit to which he is a stranger." Richards v. Jefferson County, 517 U.S. 793, 800 n.5 (1996).

[18] Taylor noted that filing a lawsuit immediately after a prior plaintiff's case was resolved in favor of the same defendant (as here) *could* be evidence of deliberate maneuvering "to obtain multiple bites of the litigatory apple." 490 F.3d at 975-76. Yet, such timing is not automatically susceptible to a nefarious inference; the timing of the later suit could have occurred by happenstance or for other perfectly legitimate reasons. See id. Accordingly, the Taylor court did not consider this factor as weighing in favor of, or against, applying the virtual-representation doctrine. Here, at the motion-to-dismiss stage, Axcan is entitled to the benefit of the doubt on this issue.

allegedly false advertising. The claims, therefore, are private. Id.

For these reasons, the Court concludes that application of the virtual-representation doctrine is unwarranted at this time. Accordingly, the Motions must be denied on this ground.

IV. The Court cannot decide at this juncture whether laches bars Axcan's claims.

The Defendants next argue that Axcan's claims are barred by laches, because "[n]ot only did Axcan wait seven years to challenge [the Defendants'] marketing [practices], it sat on the sidelines for four years while its attorney prosecuted an identical lawsuit . . . on behalf of an identically situated plaintiff." (Ethex & KV Mem. at 21.) At this stage of the litigation, the Court cannot agree.

Laches is an equitable doctrine "premised upon the same principal that underlies the statute of limitations: the desire to avoid unfairness that can result from the prosecution of stale claims." Midwestern Mach. Co. v. Nw. Airlines, Inc., 392 F.3d 265, 277 (8th Cir. 2004). In order for laches to apply, (1) a plaintiff must have unreasonably and inexcusably delayed commencing his action and (2) the defendant must have suffered prejudice as a result. Id. (quoting Goodman v. McDonnell Douglas Corp., 606 F.2d 800, 804 (8th Cir. 1979)). Because a court asked to apply laches must determine the reasonableness of – and, hence, the reasons and excuses for – the plaintiff's delay in filing suit, as well as the resulting prejudice suffered by the defendant, laches generally cannot be decided "on a motion for summary judgment, let alone a motion to dismiss." United States v. Portrait of Wally, No. 99-Civ.-9940, 2002 WL 553532, at *22 (S.D.N.Y. Apr. 12, 2002); accord, e.g.,

Kling v. Hallmark Cards, Inc., 225 F.3d 1030, 1041 (9th Cir. 2000) ("because a claim of laches depends on a close evaluation of all the particular facts in a case, it is seldom susceptible of resolution by summary judgment") (internal quotation marks omitted); Jeffries v. Chicago Transit Auth., 770 F.2d 676, 679 (7th Cir. 1985); Goldberg v. Cameron, 482 F. Supp. 2d 1136, 1152 (N.D. Cal. 2007); see also Azalea Fleet, Inc. v. Dreyfus Supply & Mach. Corp., 782 F.2d 1455, 1458 n.2 (8th Cir. 1986) (noting the "fact-bound nature of the laches issue").[19]

Here, the Court concludes that it is not in a position, at this time, to opine on the merits of the Defendants' laches defense. Axcan makes several arguments concerning the reasons for its delay – such as its purported efforts to convince the Defendants to cease their "false" advertising – that go beyond the pleadings. Axcan must be afforded the opportunity to develop and present evidence on these issues. Moreover, prejudice cannot exist here unless the Defendants "ha[ve] changed [their] position[s] in a way that would not have occurred if [Axcan] had not delayed." Goodman, 606 F.2d at 809 n.17. In other words, if the Defendants' conduct would have been the same regardless of whether Axcan sued earlier, then they cannot demonstrate any "change" in their position as a result of Axcan's delay and, hence, they cannot demonstrate prejudice. According to Axcan, that is precisely the case, as evidenced by Defendants continuing their allegedly false advertising

[19] The Defendants correctly note that some courts have applied laches at the motion-to-dismiss stage. (See Ethex & KV Reply at 2 (citing cases).) The greater weight of authority, however, holds that a laches defense can be resolved, if at all, only on a motion for summary judgment.

after having been sued by Solvay. (Mem. in Opp'n at 39-40.) Once again, the Court is not in a position to answer whether the Defendants would have changed their (allegedly) improper advertising had Axcan commenced suit earlier; they are entitled to obtain discovery on this issue. Finally, Axcan may be able to defeat the application of laches if it is able to show that the Defendants' conduct was willful or that they intended to engage in false advertising. See, e.g., Danjaq LLC v. Sony Corp., 263 F.3d 942, 956-57 (9th Cir. 2001); Deere & Co. v. MTD Holdings, Inc., 70 U.S.P.Q.2d 1009, 1027 (S.D.N.Y. 2004). As before, Axcan is entitled to discover facts that would support such an argument.

Accordingly, the Court will not dismiss Axcan's claims on the ground of laches.[20]

V. To the extent that Axcan's claims are based on "compare to" and "alternative to" advertising, the claims may stand.

In addition to alleging that the Defendants have engaged in false advertising because they market their drugs as "identical in formulation to Ultrase," Axcan also alleges that the Defendants have falsely suggested that their drugs are "generic equivalent substitute[s] for Ultrase" by advertising their drugs as "alternative[s] to" Ultrase and by "invit[ing] pharmacists and others to compare the labeled ingredients in their drugs with Ultrase." (Compl. ¶¶ 38, 47.) To the extent that Axcan's claims are based on such "comparative" and "alternative" advertising, the Defendants argue that the claims fail as a matter of law. The

[20] The parties make several additional arguments concerning laches, such as whether it may bar a Lanham-Act claim for damages (as opposed to injunctive relief) and whether, and in what circumstances, a presumption of laches may apply. Because the Court concludes that the applicability of laches cannot be addressed in the current procedural posture of this case, it need not wade into these arguments at this time.

Court does not agree.

The Defendants posit that comparative advertising is legal and, as a result, that "the Lanham Act cannot be used to prevent an advertiser from referring to its product as an 'alternative' to a competitor's product or from inviting consumers to 'compare' the two products." (Impax & Global Mem. at 18.) Yet, several courts have held that advertisements inviting consumers to "compare" one product to another can be misleading in context.

For example, in Nutrition & Fitness, Inc. v. Mark Nutritionals, Inc., the defendant manufactured a dietary supplement called "Body Solutions," and the plaintiff marketed a competing supplement whose label stated "Compare to Body Solutions." The defendant brought a counterclaim against the plaintiff for false advertising under the Lanham Act, and the plaintiff moved to dismiss, arguing that its label could not amount to false advertising as a matter of law. The court rejected that argument, stating:

> In order to form the base of a false advertising claim, the offending statement must be "either false on its face or, although literally true, likely to mislead and to confuse consumers given the merchandising context." Accordingly, "bald assertions of superiority or general statements of opinion" do not result in a [Lanham Act] violation. Similarly, statements that are "exaggerated advertising, blustering and boasting upon which no reasonable buyer would rely" are more properly considered "puffery" and are not actionable under the Lanham Act's false advertising provision. Other sources have described puffery as "a general claim of superiority over a comparative product that is so vague, it would be understood as a mere expression of opinion."
>
> Plaintiff maintains that the "Compare to Body Solutions" statement on its own product does not make a detailed or specific assertion of measurable fact. As such, Plaintiff contends that the statement Defendants complain of is merely nonactionable "puffery." The court disagrees. This is not an instance where the alleged false advertising claims are broad assertions of superiority in the field. Instead, by referencing a particular competing product, that is, the

> Body Solutions line, Plaintiff's invitation to "compare" does not qualify as a vague claim of superiority. *Unlike more subjective terms often used in advertising, "compare" suggests that a product's performance has in fact been tested and verified. Although "Compare to Body Solutions" by itself is not a false statement, Defendant alleges that the statement is misleading in that it leads consumers to believe that Plaintiff's products have been tested and are equivalent in efficacy or content with the Body Solutions line when they in fact are not.*

202 F. Supp. 2d 431, 435-36 (M.D.N.C. 2002) (emphasis added) (citations omitted); see also Clorox Co. P.R. v. Procter & Gamble Commercial Co., 228 F.3d 24, 37 (1st Cir. 2000) (advertisement inviting consumers "Compare to your detergent . . . Whiter is not possible" actionable as false advertising under Lanham Act); Cartier, Inc. v. Deziner Wholesale, L.L.C., No. 98-Civ.-4947, 2000 WL 34171, at *4-5 (S.D.N.Y. Apr. 3, 2000) (denying summary judgment on false-advertising claim where label on defendant's product invited consumers to compare prices, quality, and style with plaintiff's product). Similarly, Axcan alleges in this case that by inviting pharmacists and others to "compare" the Defendants' pancreatic-enzyme drugs to Ultrase, they falsely suggest that the drugs are equivalent in efficacy or ingredients. (Compl. ¶¶ 38, 47.)

Courts have also held that advertising one product as an "alternative to" another may violate the Lanham Act. In Healthpoint, Ltd. v. Ethex Corp., Civil No. SA-01-CA-646, 2004 WL 2359420 (W.D. Tex. July 14, 2004), for example, the court held that Ethex's advertising of its wound-debridement ointment as an alternative to the plaintiff's competing ointment was actionable because it could suggest that the two products had the "same active ingredients in the same quantities." Id. at *16. Solvay I reached the same conclusion. See

2006 WL 738095, at *3 (D. Minn. Mar. 22, 2006). Following those rulings here, Axcan can succeed on its "alternative to" claims if it can prove that the Defendants' advertising suggests that Pangestyme and Lipram contain the same ingredients, in the same quantities, as Ultrase, when in fact they do not. (Compl. ¶¶ 37-38, 46-47.)

Accordingly, Axcan may proceed with its false-advertising claims based on the Defendants' "compare to" and "alternative to" advertising.

VI. Axcan's claims are sufficiently pleaded.

Finally, the Defendants argue that Axcan's claims are not pleaded with the requisite specificity under Federal Rule of Civil Procedure 9(b). This argument lacks merit.

As an initial matter, it is not entirely clear that Rule 9(b)'s strictures apply to Lanham-Act claims. As Axcan points out in its response, there is a split of authority on this issue. Compare, e.g., Conditional Ocular Enhancement, Inc. v. Bonaventura, 458 F. Supp. 2d 704, 709 (N.D. Ill. 2006) ("Claims that allege . . . false advertising under the Lanham Act are subject to the heightened pleading requirements of Fed. R. Civ. P. 9(b).") with John P. Villano, Inc. v. CBS, Inc., 176 F.R.D. 130, 131 (S.D.N.Y. 1997) ("a claim of false advertising under [the Lanham Act] falls outside the ambit of Rule 9(b) and may not be subject of any heightened pleading requirement"); see also Nutrition & Fitness, Inc., 202 F. Supp. 2d at 434 (recognizing that several district courts have applied heightened pleading requirement but that no appellate court had opined on the propriety of doing so). Indeed, the Villano court articulates several persuasive reasons why Lanham-Act claims should not be subject to any pleading-with-particularity rule. See 176 F.R.D. at 131.

In any event, assuming *arguendo* that a heightened pleading requirement applies to Axcan's claims, the Court concludes that such requirement has been satisfied here. Rule 9(b) does not require that the exact particulars of every allegedly instance of "false" advertising be specified in the Complaint. See 5A Charles A. Wright & Arthur R. Miller, Federal Practice & Procedure: Civ. 2d § 1297 (3rd ed. 2007). Rather, that Rule is satisfied if the plaintiff's complaint sufficiently apprises the defendant "of the nature of the claim and the acts . . . relied upon by the plaintiff" as constituting the unlawful conduct. Id.; accord Commercial Prop. Inv., Inc. v. Quality Inns Int'l, Inc., 61 F.3d 639, 644 (8th Cir. 1995). The Complaint here clearly apprises the Defendants of the acts relied upon by Axcan in support of its claims. Stated differently, Axcan has pleaded the "who [the Defendants], what [false advertising], where [in ads targeted to drug databases, wholesalers, and pharmacies], when [since the late 1990's], and how [falsely claiming their drugs are generic equivalents or substitutes]" of its claims. Great Plains Trust Co. v. Union Pac. R. Co., 492 F.3d 986, 995 (8th Cir. 2007). The sheer length and breadth of the Defendants' Memoranda indicate that they have been fully apprised of the nature of Axcan's claims and can adequately prepare responses thereto. Solvay II involved claims pleaded in similar fashion, see 298 F. Supp. 2d at 885-86, and the Court reached the same conclusion; this Court perceives no reason to deviate from that ruling.

CONCLUSION

Based on the foregoing, and all the files, records, and proceedings herein, **IT IS ORDERED** that Defendants Ethex's and KV's Motion for Judgment on the Pleadings (Doc.

No. 33) and Defendants Impax's and Global's Motion to Dismiss (Doc. No. 41) are **GRANTED IN PART** and **DENIED IN PART** as follows:

1. The Motions are **GRANTED** to the extent that they argue that claims for conduct occurring before June 1, 2001, are barred by the statute of limitations, and claims based on such conduct are **DISMISSED WITH PREJUDICE**; and

2. In all other respects, the Motions are **DENIED**.

Dated: October 19, 2007

s/Richard H. Kyle
RICHARD H. KYLE
United States District Judge